

**IN THE UNITED STATES DISTRICT COURT FOR THE  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

In Re:	:	
	:	
Ethicon, Inc. Pelvic Repair System	:	
Products Liability Litigation	:	Civil Action No. MDL 2327
	:	

**ETHICON MDL PLAINTIFFS' MEMORANDUM OF LAW  
IN OPPOSITION TO THE SECANT MEDICAL DEFENDANTS'  
MOTION TO STAY ENFORCEMENT OF A SUBPOENA**

Plaintiffs respectfully file this memorandum in opposition to the Motion of Secant Medical, Inc., Secant Medical LLC, and Prodesco, Inc. (together "Secant Medical") for a stay of the enforcement of subpoenas that Plaintiffs served in this proceeding. Those subpoenas were properly served and Secant does not suggest the contrary. Secant instead says that its obligation to respond should be postponed until the Court decides whether Secant is immune from suit under the Biomaterials Access Assurance Act ("BAAA"), 21 U.S.C. §§ 1601-06. This unusual motion should be denied for several reasons, including that the BAAA expressly contemplates discovery to determine the threshold question of immunity.<sup>1</sup>

**I. Factual Background**

Secant Medical is the knitter, manufacturer and co-designer of polypropylene mesh that Ethicon cuts into specific shapes and then sells as a transvaginal mesh implant. The mesh that Secant designs and manufactures is the sole product that is actually implanted into the woman's

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<sup>1</sup> As Secant filed an identical motion in the United States District Court for the Eastern District of Pennsylvania, the Court which issued the Subpoena, Secant has violated both U.S.D.C. S.D. W. Va. L.R. Civ. P. 37.1(b) and U.S.D.C. E.D. Pa. L.R. Civ. P. 26.1(f) by failing to meet and confer prior to filing this motion and to certify that it had done so. Indeed, Secant's counsel simply sought an extension to respond to this discovery and deliberately failed to mention that its purpose in seeking the extension was not to respond at all, but simply to file its motion to stay proceedings.

body and is the product that causes the extensive injuries that have given rise to the Ethicon MDL. Secant Medical's contractual relations with Ethicon date back to at least the early 1990s and include a patent for the design and manufacturing of the mesh.

In the Ethicon MDL, Plaintiffs sought discovery from Secant Medical through a Subpoena they originally served on or about April 17, 2013 and reissued on September 10, 2013. *See* Subpoena issued September 10, 2013 Subpoena, attached as Exhibit "A".

At the time these Subpoenas issued, Secant Medical was a third-party in the Ethicon MDL. Plaintiffs later sued Secant Medical directly based on the materials Ethicon produced during discovery in this MDL. In particular, Plaintiffs filed cases against Secant Medical (along with Ethicon and other defendants) in the Philadelphia County Court of Common Pleas. Claiming that Secant was a citizen of the Commonwealth of Virginia despite Secant's admission that it is a citizen of the Commonwealth of Pennsylvania, *see*, Excerpts from Secant's Memorandum of Law in Support of its Motion to Dismiss [7, July 17, 2013] at 11, "Delacruz v. Ethicon, Inc. et al.," No. 2:13-cv-4088, United States District Court for the Eastern District of Pennsylvania, attached as Exhibit "B," Ethicon removed those cases to the Eastern District of Pennsylvania, arguing that Secant was fraudulently joined because it is immune from suit under the BAAA and therefore Secant's Pennsylvania citizenship should be disregarded for purposes of assessing removability under the home-state defendant rule set forth in 28 U.S.C. § 1441. In October 2013, the Judicial Panel on Multidistrict Litigation transferred the removed cases to the MDL. There are no discovery requests in the Ethicon MDL against Secant Medical apart from the instant Subpoenas.

Additional plaintiffs have recently filed claims against Secant Medical (among other defendants) in the Philadelphia County Court of Common Pleas. These claims generally involve

New Jersey plaintiffs and hence there is no diversity of citizenship that could support removal since Ethicon is a New Jersey defendant. Secant Medical has moved for dismissal from these Philadelphia cases on grounds the BAAA immunizes Secant Medical from suit.

The Philadelphia Court of Common Pleas denied Secant Medical's motions to dismiss under the BAAA and has ordered that discovery move forward to develop a record around the BAAA immunity questions. *See* "Hespe v. Ethicon Women's Health and Urology," Phila. CCP, July Term 2013, No. 0947, Order dated October 23, 2013, attached as Exhibit "C". Previously, Secant agreed to the entry of a Case Management Order in the Philadelphia Court of Common Pleas. That Order provided for discovery against it to take place until December 1, 2014. *See* September 11, 2013 Case Management Order – Complex Track at ¶2, Hansen v. Ethicon, Inc., et al., May Term, 2013, No. 03785, Philadelphia Court of Common Pleas, attached as Exhibit "D".

On September 18, 2013, the Philadelphia plaintiffs served Secant Medical with a notice for the deposition of Mr. Erik Nadeau, Secant Medical's chief executive officer, who has executed multiple affidavits in support of Secant's myriad filings and has claimed that Secant Medical is a mere seller of biomaterials and hence immune under the statute. *See* Notice of Deposition, attached as Exhibit "E". The notice of deposition included requests for documents that Mr. Nadeau is to bring to the deposition. The discovery sought through this notice of deposition is basically the same as that sought through the Ethicon MDL Subpoenas.

## **II. Legal Analysis**

"A stay is not a matter of right, even if irreparable injury might otherwise result." *Nken v. Holder*, 129 S. Ct. 1749, 1760 (2009). Rather, it is "an exercise of judicial discretion," and "the propriety of its issue is dependent upon the circumstances of the particular case." *Id.* The

party seeking a stay bears the heavy burden of justifying the exercise of that discretion. *Id.*

Against this backdrop, the Court should deny Secant Medical's stay request for four reasons.

*First*, Plaintiffs have a statutory right under the BAAA to take discovery on whether the BAAA immunizes Secant from suit. The question is whether Secant Medical is a "biomaterials supplier" for purposes of the statute. If the former, Secant Medical is immune. If not, no immunity attaches. The BAAA specifically permits discovery so a factual record can be developed on this point. As Section 1605(c) of the BAAA provides:

(3) Discovery with respect to a biomaterials supplier. A biomaterials supplier shall be subject to discovery in connection with a motion seeking dismissal or summary judgment on the basis of the inapplicability of section 5(d) or the failure to establish the applicable elements of section 5(d) solely to the extent permitted by the applicable Federal or State rules for discovery against nonparties.

21 U.S.C. § 1605(c)(3).

The discovery contemplated by Section 1605(c)(3) means that a motion to dismiss under the BAAA is slightly different than the "usual" motion to dismiss. Motions to dismiss typically are based solely on a pleading. Under the BAAA, a motion to dismiss also may involve evaluating a factual record on whether the defendant is a biomaterials supplier. This is made clear by Section 1605(d) of the BAAA, which specifically contemplates the use of discovery when deciding a BAAA motion to dismiss:

(1) Effect of motion to dismiss on discovery.

(A) In general. Except as provided in subparagraph (B), if a defendant files a motion to dismiss under subsection (a), no discovery shall be permitted in connection with the action that is the subject of the motion, other than discovery necessary to determine a motion to dismiss for lack of jurisdiction, until such time as the court rules on the motion to dismiss.

(B) Discovery. If a defendant files a motion to dismiss under subsection (a)(3) on the grounds that it did not furnish raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications, the court may permit discovery limited to issues that are directly relevant to-

(i) the pending motion to dismiss; or

(ii) the jurisdiction of the court.

21 U.S.C. § 1605(d)(1).

*Second*, Ethicon made the BAAA immunity a jurisdictional issue when it removed cases filed in Philadelphia County on grounds that Secant was fraudulently joined (saying that the BAAA rendered Secant immune from suit). Whether Secant Medical is immune under the BAAA will determine federal jurisdiction. This reality underscores the importance of the discovery permitted by the BAAA. As Ethicon is attempting to use the BAAA as a sword, Secant Medical should be required to provide the discovery the BAAA contemplates and requires. The requested discovery will enable the Court to make a crucial threshold decision on federal jurisdiction.

*Third*, a stay of discovery against Secant Medical would waste of judicial resources. As noted above, Secant Medical has been sued in cases pending in Philadelphia County. Secant Medical has moved for dismissal in those cases under the BAAA. The Philadelphia courts denied Secant Medical's motion without prejudice and directed that discovery go forward on the issues crucial to a BAAA analysis. *See* Exhibit C. In a related case, the Court also entered an order providing for discovery on these issues until December 1, 2014. *See*, Exhibit D. Since the discovery sought in the Ethicon MDL is the same as the discovery sought in Philadelphia actions, Secant Medical is already obliged to produce documents concerning its role in the

design, manufacturing, testing, and marketing of the polypropylene mesh implants at issue. The stay should be denied for this reason as well.

*Fourth*, Secant Medical's concerns over the "scope" of discovery are a red herring. Discovery under the BAAA is required to determine whether Secant Medical is immune under the BAAA and hence whether federal jurisdiction exists over the removed cases. That discovery must proceed promptly so these basic questions can be resolved.

### **III. Conclusion**

For all of these reasons, Plaintiffs respectfully request that the Court deny Secant Medical's Motion to Stay Enforcement of a Subpoena and provide such further relief as the Court deems just and proper.

Respectfully submitted,

**Kline & Specter, P.C.**

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